UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/458,298	12/10/1999	JOHN FIKES	18623-014600	8697

26111 7590 10/03/2003

STERNE, KESSLER, GOLDSTEIN & FOX PLLC
1100 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005

EXAMINER	
HADDAD, MAHER M	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/458,298	FIKES ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-40* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

   1. Claims 1-4, 7-9, 37-38, drawn to a peptide composition, wherein the peptide is a peptide of A1 supermotif and analog thereof, a vaccine and a kit, classified in Class 530, subclass 327.

   2. Claims 1-4,7-9, 37-38, drawn to a peptide composition, wherein the peptide is a peptide of A2 supermotif/A*0201 motif and analog thereof, a vaccine and a kit, classified in Class 530, subclass 327.

   3. Claims 1-4, 7-9, 37-38, drawn to a peptide composition, wherein the peptide is a peptide of A3 supermotif and analog thereof, a vaccine and a kit, classified in Class 530, subclass 327.

   4. Claims 1-4, 7-9, 37-38, drawn to a peptide composition, wherein the peptide is a peptide of A24 supermotif and analog thereof, a vaccine and a kit, classified in Class 530, subclass 327.

   5. Claims 1-4, 7-9, 37-38, drawn to a peptide composition, wherein the peptide is a peptide of B7 and analog thereof, a vaccine and a kit, classified in Class 530, subclass 327.

   6. Claims 1-4, 7-9, 37-38, drawn to a peptide composition, wherein the peptide is a peptide of B27 and analog thereof, a vaccine and a kit, classified in Class 530, subclass 327.

   7. Claims 1-4, 7-9, 37-38, drawn to a peptide composition, wherein the peptide is a peptide of B58 and analog thereof, a vaccine and a kit, classified in Class 530, subclass 327.

   8. Claims 1-4, 7-9, 37-38, drawn to a peptide composition, wherein the peptide is a peptide of B62 and analog thereof, a vaccine and a kit, classified in Class 530, subclass 327.

   9. Claims 1-4, 7-9, 37-38, drawn to a peptide composition, wherein the peptide is a peptide of A1 motif and analog thereof, a vaccine and a kit, classified in Class 530, subclass 327.

   10. Claims 1-4, 7-9, 37-38, drawn to a peptide composition, wherein the peptide is a peptide of A3 motif and analog thereof, a vaccine and a kit, classified in Class 530, subclass 327.

   11. Claims 1-4, 7-9, 37-38, drawn to a peptide composition, wherein the peptide is a peptide of A11 and analog thereof, a vaccine and a kit, classified in Class 530, subclass 327.

12. Claims 1-4, 7-9, 37-38, drawn to a peptide composition, wherein the peptide is a peptide of A24 motif and analog thereof, a vaccine and a kit, classified in Class 530, subclass 327.

13. Claims 10, 37-38, drawn to a peptide composition, wherein the peptide is a peptide of Table XXII and analog thereof, a vaccine and a kit, classified in Class 530, subclass 327.

14-25 Claims 5-6, drawn to a pharmaceutical composition, wherein the composition comprising a peptide in a form of nucleic acids that encodes the peptide of A1 supermotif, A2 supermotif/A*0201 motif, A3 supermotif, A24 supermotif, B7, B27, B58, B62, A1 motif, A3 motif, A11, A24 motif, **RESPECTIVELY**, classified in Class 536, subclass 23.1.

26-38 Claims 11, 14, 15, 18-19, drawn to a method for inducing a cytotoxic T lymphocyte response with a peptide of A1 supermotif, A2 supermotif/A*0201 motif, A3 supermotif, A24 supermotif, B7, B27, B58, B62, A1 motif, A3 motif, A11, A24 motif,Table XXII or Table XXIII, **RESPECTIVELY,** classified in Class 424, subclass 193.1.

40-53 Claims 11-13, 15-17, 19, drawn to a method for inducing a cytotoxic T lymphocyte response with a peptide in a form of nucleic acids that encode the peptide of A1 supermotif, A2 supermotif/A*0201 motif, A3 supermotif, A24 supermotif, B7, B27, B58, B62, A1 motif, A3 motif, A11, A24 motif or Table XXII, or Table XXIII, **RESPECTIVELY,** classified in 514, subclass 44.

54 Claims 20-23, 27 and 37-38, drawn to a pharmaceutical composition comprising a peptide of Table XIX or Table XX that comprises at least one HLA DR molecule of an HLA DR supertype and analog thereof, vaccine and a kit, classified in Class 530, subclass 328.

55 Claims 24-26, drawn to a pharmaceutical composition comprising a peptide, wherein the peptide in a form of nucleic acids that encode the peptide of Table XIX or Table XX comprises least one HLA DR molecule of an HLA DR supertype, classified in Class 536, subclass 23.1.

56 Claims 28, 32, 35, 36, drawn to a method for inducing a helper T lymphocyte response with a peptide from Table XIX or XX which comprises at least one HLA DR molecule of an HLA DR supertype for an HLA class II molecule, classified in Class 424, subclass 193.1.

57 Claims 28-30, 33-34, drawn to a method for inducing a helper T lymphocyte response with a peptide in a form of nucleic acids that encode the peptide from Table XIX or XX, classified in Class 514, subclass 44.

58-71 Claims 39-40, drawn to a method for monitoring or evaluating an amnune response to a tumor with a peptide of A1 supermotif (table VII), A2 supermotif/A*0201 motif (table VIII_, A3 supermotif (table IX), A24 supermotif(table X), B7 (table XI), B27 (table XII), B58 (table XIII), B62 (table XIV), A1 motif (table XV), A3 motif (table XVI), A11 (table XVII), A24 motif (table XVIII), table XIX, table XX or Table XXII, **RESPECTIVELY,** classified in Class 424, subclass 193.1.

2. Groups 1-25 and 54-55 are different products. Peptides, and nucleic acids encoding the peptides differ with respect to their structures and physicochemical properties; therefore each product is patentably distinct.

3. Groups 26-53 and 56-71 are different methods. A method of inducing a cytotoxic T response, a method of inducing a helper T lymphocyte response and a method for monitoring or evaluating an immune response differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

4. Groups 1-25, 54-55 and 26-53, 56-71 are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product could be used to detect CTL in an in vitro assay.

5. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper.

Species Election

6. Irrespective of whichever group applicant may elect, applicant is further required under 35 US 121 (1) to elect a single disclosed species to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

A. If any one of Group 1-76 is elected, applicant is required to elect a single specific peptide from tables VII-XX or Table XXII-XXIII for the elected claims of the invention which applicant choose. These are distinct species because their structures are different and encode peptides that are structurally and functionally distinct and derived from different proteins with different functions.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently.

7. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (703) 306-3472. The examiner can normally be reached Monday through Friday from 8:00 AM to 4:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 872-9307.

Maher Haddad, Ph.D.
Patent Examiner
Technology Center 1600
September 30, 2003

PATRICK J. NOLAN, PH.D.
PRIMARY EXAMINER
10/1/03